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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,300	12/06/2001	Hiroyuki Tokunaga	2001-1339A	9726
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WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021				
			EXAMINER NOGUEROLA, ALEXANDER STEPHAN	
			ART UNIT 1753	PAPER NUMBER

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,300

Applicant(s)

TOKUNAGA ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09252001.
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 06032004.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Specification

1. The abstract must be 150 words or less. MPEP 608.01(b).

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-8, drawn to a measuring apparatus or biosensor, classified in class 204, subclass 400 .

Group II, claims 9-11, drawn to a standard solution for a biosensor, classified in class 252, subclass 408.1.

3. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group I does not explicitly or implicitly mention an exclusive standard solution, let alone one for suppressing oxidation current. Also, the invention of Group II does not require an electrochemical biosensor.

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4. During a telephone conversation with Nils Pedersen on June 03, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. Claims 1-4, 7, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a) Claim 1: the structural limitations being claimed for the measuring apparatus are indefinite. The only clear structural limitations for the measuring apparatus are in the

preamble of the claim – the body of the claim only recites intended use, except, perhaps, for an implicit limitation that the device be capable of allowing current to flow between the third electrode and the counter electrode or between the third electrode and the working electrode. The examiner suggests Applicant recast claims 1-4 as method claims;

b) Claim 1: it is not clear whether a method or apparatus is being claimed. The preamble states that the invention is directed to “[a] measuring apparatus **using** a biosensor [emphasis added].” However, structural limitations are only found in the preamble of the claim, the body of the claim only recites intended use, and no positively recited method of using steps are in the claim at all;

c) Claims 2-4 do not appear to further structurally limit the measuring apparatus of claim 1, but only recite intended use;

d) Claim 5, line 3-4: what does Applicant mean by electrodes on electrodes?

e) Claim 7 recites the limitation "materials of the third electrode" in line 2. There is insufficient antecedent basis for this limitation in the claim;

f) Claim 7: this claim does not further limit claim 5 because the voltage applied to the biosensor is not specified and is only intended use as claim 5 is directed to a device not a method of using a device; and

g) Claim 8 recites the limitation "materials of the third electrode" in line 2. There is insufficient antecedent basis for this limitation in the claim.

7. Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Ikeda et al. (US 5,650,062), hereafter "Ikeda."

Addressing claims 1-4, Ikeda teaches a measuring apparatus using a biosensor, which has a reaction layer which reacts with a substance to be measured in a sample solution, on a working electrode, a counter electrode, and a third electrode provided on an insulating substrate, so as to bridge the respective electrodes (abstract and col. 13, ll. 28-59). Note that there does not appear to be any further structural requirement to the apparatus being claimed other than possibly an implicit limitation that the device be capable of allowing current to flow between the third

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electrode and the counter electrode or between the third electrode and the working electrode (see the rejection under 35 U.S.C. 112, second paragraph, above), which is also taught by Ikeda (col. 4, ll. 6-25, which teaches a switching means for allowing current to flow between the third electrode and the counter electrode or between the third electrode and the working electrode).

For claims 2-4 note that no further structural limitations on the measuring apparatus of claim 1 have been found in these claims (see the rejection of claims 2-4 under 35 U.S.C. 112, second paragraph, above).

Addressing claim 5, Ikeda teaches a biosensor comprising a reaction layer which reacts with a substance to be measured in a sample solution so as to bridge the respective electrodes, on a working electrode, a counter electrode, and a third electrode provided on an insulating substrate (abstract and col. 13, ll. 28-59), and

a connection terminal which is electrically connected to the working electrode, the counter electrode and the third electrode, respectively, on the insulating substrate (col. 4, ll. 6-25, which teaches a switching means for allowing current to flow between the third electrode and the counter electrode or between the third electrode and the working electrode).

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Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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13. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Ikeda et al. (US 5,650,062), hereafter "Ikeda" in view of Saurer et al. (US 5,395,504), hereafter "Saurer."

Addressing claims 6-8, Ikeda teaches a biosensor comprising a reaction layer which reacts with a substance to be measured in a sample solution so as to bridge the respective electrodes, on a working electrode, a counter electrode, and a third electrode provided on an insulating substrate (abstract and col. 13, ll. 28-59), and

a connection terminal which is electrically connected to the working electrode, the counter electrode and the third electrode, respectively, on the insulating substrate (col. 4, ll. 6-25, which teaches a switching means for allowing current to flow between the third electrode and the counter electrode or between the third electrode and the working electrode).

The third electrode and the working electrode have the same composition (col. 13, ll. 28-48). Ag/AgCl is the most commonly used reference electrode material (see in Saurer col. 5, ll. 39-42). Barring evidence to the contrary, such as unexpected results, the choice of reference electrode from known reference electrodes is just a matter of optimizing the biosensor or balancing cost with acceptable accuracy.

For claim 7, note that this claim does not further patentably restrict claim 5 (see the rejection of claim 7 under 35 U.S.C. 112, second paragraph, above). So, the rejection of claim 5 above under 35 U.S.C. 103(a) also applies to claim 7.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguera
Primary Examiner
AU 1753
June 3, 2004